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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 08/397,225 | 03/28/1995 | MICHEL PERRICAUDET | EX93015G1-US | 5785 |
| 29693 | 7590 | 12/23/2005 | EXAMINER | |
| WILEY, REIN & FIELDING, LLP ATTN: PATENT ADMINISTRATION 1776 K. STREET N.W. WASHINGTON, DC 20006 | | | PRIEBE, SCOTT DAVID | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1633 | | |

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 08/397,225 | PERRICAUDET ET AL. |
| | Examiner | Art Unit |
| | Scott D. Priebe, Ph.D. | 1633 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 November 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 36-39 and 43-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 43 and 44 is/are allowed.
- 6) Claim(s) 36-39, 45-84 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

The Group and/or Art Unit designation of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Primary Examiner Scott D. Priebe, Ph.D., Group Art Unit 1633.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The provisional double-patenting rejection over application 10/301,085 is withdrawn since Applicant's failure to respond to the Office action of 4/28/05 constitutes abandonment of the '085 application.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 77 recites "E2A gene." The specification provides no antecedent basis for this term. The E2A region (gene) of human group C adenovirus encodes the 72K protein, which is described in the specification, e.g. page 12, line 11. It is suggested that page 12, line 11, of the specification be amended to identify the E2A region as the region encoding the 72K protein, whereby providing proper antecedent basis for the term in claim 77.

Claim Rejections - 35 USC § 112

Claims 36-39 remain rejected and claims 45-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record set

forth in Paper No. 51 on pages 58-72, as applied to claims 34 and 42, and the additional reasons set forth in the Office action of 5/5/05. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 36-39 have been amended to limit the adenovirus to a human group C adenovirus, but have not been limited to embodiments wherein the E4 genes, and optionally the E1 and E3 genes, are the only non-functional adenoviral genes. Similarly, new claims 45-68 and 81-84 are directed to adenovirus wherein E1 and E4 genes, and optionally E3 genes, have been rendered non-functional, or E1 and E2A genes, and optionally E4 genes, have been rendered non-functional. As the claims are written, more adenoviral genes than those recited may be non-functional. See for example claim 53, which further limits claim 45, which does not mention E3 genes, by specifying that E3 genes are also non-functional. Claims 36-39, 45-68, and 81-84 embrace embodiments wherein one or more of E2B or L1-L5 genes, for example, are also rendered non-functional. Claims 69-80 are directed to cell lines comprising, integrated into its genome, the adenovirus genes necessary to complement the adenovirus of claims 45, 53, or 61, which would also embrace adenoviral genes that are not explicitly mentioned in the claims, e.g. one or more of E2B or L1-L5 genes. Furthermore, these claims still embrace non-human cell lines, which the specification has not taught, that would be capable of complementing human group C adenovirus. Thus, the claims still embrace embodiments the Board held were not enabled.

This rejection would be overcome by limiting the non-functional adenoviral genes in the adenovirus to those explicitly recited, i.e. all other adenoviral genes are present, and the cell lines

to human cells that do not comprise any adenoviral genes other than the E1 genes, the E2 gene encoding the 72K protein, and the E4 genes, as appropriate. If such an amendment is made in claim 45, it would be necessary to specify in claim 45 that non-functional E3 genes were optional so that claim 53 would properly depend from claim 45.

Applicant's arguments filed 11/14/05 have been fully considered but they are not persuasive. Applicant (Reply, page 13) indicates that claims 36-39 were amended as suggested in the Office action of 5/5/05. However, the amendment did not limit the non-functional adenoviral genes in the adenovirus to E4 genes, and optionally E1 and E3 genes, as was suggested in the Office action (page 11). Nor does claim 77 recite that the cell line does not complement late genes, as asserted.

Claims 73-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 73-76 are directed to cell lines that comprise E1 under its own promoter, and "the E3 and E4 are under control of an inducible promoter". The latter limitation is new matter that is not supported by the original disclosure. The original specification says nothing about including an E3 gene in the genome of a complementing cell line, much less under control of an inducible promoter or the same inducible promoter that controls the E4 gene, as recited. Page 12, lines 5-9, do not mention the E3 region.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633